

### REMARKS

Entry of the foregoing amendments, and reexamination and reconsideration of the subject application, pursuant to and consistent with 37 C.F.R. § 1.104 and § 1.112, and in light of the following remarks, are respectfully requested.

#### Amendments

Claim 1 has been amended to recite that the subunguicide is sufficiently hard to be inserted between the nail plate and the hyponychium (as supported, e.g., at the paragraph bridging pages 7 and 8 of the application). Claim 2 has been amended to require that the method introduce the subunguicide past the hyponychium, and claim 6 specifies that the method does not require penetrating the nail plate. No new matter is added.

#### Rejections under 35 U.S.C. §112[2]

The rejection of claim 8 hereunder is moot in light of the amendment correcting its dependency to claim 7.

Regarding "high" pressure in claim 13, that claim term is straightforward and should be given its ordinary meaning as would one of ordinary skill in the art, *Golden Blount Inc. v. Robert H. Peterson Co.*, 70 USPQ2d 1624 (Fed. Cir. 2004). There is nothing in the rejection supporting *why* such a relative term would not be understood by one of ordinary skill in the art, *Ex parte Logan*, 20 USPQ2d 1465 (B.P.A.I. 1991). Reference is made at page 8 (lines 16-21) of the present application to jet injectors (see <http://www.cdc.gov/nip/dev/jetinject.htm>). Accordingly, a "high" pressure is sufficiently clear and concise in the context of the present claim.

Regarding "flowably forced" in claim 14, flowable types of compositions are described at page 7 (last full paragraph). It is known that applying pressure or shear to certain semi-solids makes them flowable. Accordingly, the term in the claim is understandable.

In light of the foregoing, these rejections should be withdrawn.

Rejections under 35 U.S.C. §102

The rejection of claims 1 and 9-11 as anticipated by Maibach (*et al.*) is respectfully traversed. Firstly, applicant coined the term "subunguicide" and so Maibach does not disclose a "subunguicide" as alleged in the rejection. Rather, Maibach teaches compositions that can be applied "to the nail and surrounding tissues" (column 14, ln. 25-30). Nowhere in Maibach is there any disclosure of a composition "sufficiently hard for insertion between the nail plate and the hyponychium" as now recited in the claims. None of the "cream, lotion, solution, gel, ointment, paste, plaster, paint, bioadhesive, or the like" mentioned by Maibach is at all hard (a medical plaster is merely harder than ointment). Accordingly, Maibach does not anticipate claim 1 as now amended, and so neither of claims 9-11.

The rejection of claims 1-5, 9, 13, and 15 as anticipated by Brem (4,180,058) is respectfully traversed. A wet dressing is not a semi-solid (which is a well-defined term), as recited in claim 1; rather, a wet dressing could be a medical plaster, which also is not a semisolid. Creams, lotions, ointments, and powders are the formulations disclosed by Brem (middle of column five), none of which are semisolid. Regarding claim 2, there is no disclosure in Brem of forcing the antifungal agent past the hyponychium to end up in contact with the nail bed. Clearly Brem is directed to drilling holes in the nail plate, widening the holes, and then treating the infection through the holes. The Office action provides absolutely no support for the allegation that an antifungal agent applied to the holes drilled in the nail plate by Brem is inherently drawn by capillary forces between the nail bed and nail plate. That allegation in the action is refuted by the number of holes (generally 4-8 for the *initial series*, see top of column five) drilled in the nail plate; if capillary forces were at work, it would seem that a large number of holes (as seen in Fig. 2C) would be unnecessary. Neither does Brem disclose that capillary action functions under the nail plate, and because the bed and plate are typically in intimate contact, there is typically no space in which the capillary forces can operate. Accordingly, the examiner is requested to support (via 37 C.F.R. §1.104(d)) the alleged inherent capillary forces acting between the nail bed and the nail plate. (If the examiner were correct, then such infections

would only need to be treated by applying a composition to the hyponychium, which composition would then migrate by capillary forces throughout the nail bed to the eponychium at the proximal end of the nail bed, but there is no such practice.) There is a know separation between the nail plate and the nail bed in an infected nail, but that separation is distal of the hyponychium (which is effectively the advancing front of the infection).

In light of the foregoing, withdrawal of these rejections is now believed to be in order.

#### Rejection under 35 U.S.C. §103

The rejection of claim 6 as obvious over Brem is respectfully traversed, especially in light of the amendment to claim 6, that the application avoids penetrating the nail plate. This is not to say that the present method cannot be used in combination with one that penetrates the nail plate (such as by Brem's drilling). Rather, the present method is patentable because there is no disclosure in the prior art to administer an antifungal to the nail bed by being forced between the nail bed and nail plate past the hyponychium rather than being administered through the nail plate as in Brem. Accordingly, this rejection should now be withdrawn.

#### Conclusion

In light of the foregoing, all of the rejections should now be withdrawn, and further and favorable action, in the form of a notice of allowance, is now in order, and such actions are earnestly solicited.